REMARKS

Claims 1-23 are pending in the Office action and are under examination. Claim 1 has been amended to clarify that the effective amount of a water-absorbent polymer is for increasing the amount of fluid in the feces. Support for the amendment can be found in Examples 4, 6 and page 7, lines 23-24, for example. Other amendments modify claim dependencies or are meant to conform the dependent claims to these amendments. It is believed that no new matter has been added by way of amendment.

Claims 1-23 stand rejected under 35 U.S.C. § 112 as lacking enablement for preventing all possible fluid overload states or patients suffering from all possible fluid overload states. Claim 1 has now been amended to clarify that the method is for increasing fluid loss into the feces. The specification provides clear support for this phrase, as set forth above. Consequently, it is believed that the rejection is now moot and the claims are enabled. Applicants kindly request that the basis for the rejection be reconsidered and that the rejection be withdrawn.

Claims 1-23 stand rejected under 35 U.S.C. § 103(a) as obvious over *Berger et al.* (US 4,470,975 in view of *Samejima et al.* (EP 0,077,956) and *Thompson* (US 5,004,603). Of the rejected Claims, only Claim 1 is independent. Applicants respectfully request that the rejection be withdrawn for the following reasons. *Berger* fails to disclose directly administering to the intestinal tract of a host a water-absorbent polymer. As the Office action has noted, the *Burger* water-absorbent polymer is not administered directly to the intestinal tract of a host. Rather it is administered orally in an uncapsulated form after being mixed with food.

As also noted in the Office action, *Samejima* fails to disclose directly administering to the intestinal tract of a host an effective amount of a water-absorbent polymer that is capable of absorbing at least 10 times its weight in physiological saline. In contrast to the present invention the *Samejima* water absorbent polymer is an excipient and only absorbs 1.2 to 1.5 times its weight in fluid. The *Samejima* use of the water absorbent polymer is in an entirely different context. In *Samejima* the polymer is not used as an active agent and its minimal absorption characteristics would not suggest to one of skill the use of its excipient as an active agent, particularly for increasing fluid loss through the feces.

Thompson also fails to remedy the defects present in *Berger* and *Samejima*. As in *Berger, Thompson* discloses feeding its ammonium polyacrylate polymers to animals, rather than directly administering the polymers to the intestine, as in the present invention. The rational behind the *Thompson* method is said to be increasing the food conversion rate, particularly for animals fed on silage and cereals. Notably, *Thompson* teaches feeding swollen polymer which would no longer be capable of absorbing at least 10 times its weight in physiological saline as in the present invention. (See Col. 2, lines 37-42). Thus, *Thompson* is directed to another purpose entirely and one of skill in the art would not be led to combine *Thompson* with either *Berger* or *Samejima* or both in such a manner as to obtain the present invention.

Secondary considerations provide further evidence of the non-obviousness of the combination. Specifically, despite a need in the art, as noted in the Berger patent (col. 1, lines 8-51) which was filed in 1977, to Applicant's knowledge the *Berger* method ultimately has failed to become a method for increasing fluid loss through the feces. Some evidence of this fact, is provided in Attachment A wherein a search of the FDA website reveals that the cross-linked *Berger* polysaccharides (SEPHADEX®) is not now a prescription drug or an over the counter drug and is not a discontinued drug. A search for the term polysaccharide, also attached at Attachment A, gives the same result. Not only does *Berger* demonstrate a long felt need but the subsequent lack of an accepted therapy demonstrates a failed attempt at providing such a therapy. Further, a search of the FDA Orange Book reveals that polyacrylates have never been an active agent for any approved medication (also attached as Attachment A), much less for increasing fluid loss into the feces, and Applicants are unaware that any fluid absorbing polymer that can absorb at least 10x its mass has been the subject of an application or approved for use as an active agent for increasing the fluid loss in the feces. The fact that *Samejima* was first published in 1985, almost 19 years before the filing date of the present application, and *Thompson* became public 13 years prior to the filing of the present invention provides further evidence that despite a long felt need, the present invention was not made obvious by any combination of the cited references.

For the foregoing reasons it is submitted that Claim 1 is patentable over *Berger et al.* (US 4,470,975 in view of *Samejima et al.* (EP 0,077,956) and *Thompson* (US 5,004,603). Likewise,

Claims 2-23 which depend from Claim 1 and therefore contain all of its limitations are allowable for at least the same reasons.

The Office Action rejected claims 1-23 on the ground of nonstatutory obviousness-type double patenting as being unpatentable over Claims 1-7 and 11-14 of U.S. Patent No. 6,908,609. For purposes of advancing the prosecution of this application, Applicants have elected to overcome such rejection through the enclosed Terminal Disclaimer, attached as Attachment B. Such election shall not be deemed an admission as to the propriety or accuracy of the Office Action's conclusions or rejections.

The Commissioner is hereby authorized to charge deposit account 02-1818 for any fees which are due and owing, please reference docket number 117878-11. Should the Examiner identify any issues which can be resolved by telephone, the Examiner is encouraged to contact the undersigned.

Respectfully submitted,

BELL, BOYD & LLOYD LLP

BY 

Robert M. Gould
Reg. No. 43,642
Customer No. 24573
312-807-4244

Dated: October 19, 2007

ATTACHMENT A

Electronic Orange Book Query

Search by Proprietary Name:
Sephadex (Type in part or all of name)

Select the list you would like to search:

- ○ Rx (Prescription Drug Products)
- ○ OTC (Over-the-Counter Drug Products)
- ◉ Disc (Discontinued Drug Products)

Submit Clear

Return to the Electronic Orange Book Home Page!

No matching records found. Use your browser's Back button to go back and enter a new search criteria.

Electronic Orange Book Query

Search by Proprietary Name:
Sephadex (Type in part or all of name)

Select the list you would like to search:

- ○ Rx (Prescription Drug Products)
- ◉ OTC (Over-the-Counter Drug Products)
- ○ Disc (Discontinued Drug Products)

Submit Clear

Return to the Electronic Orange Book Home Page!

No matching records found. Use your browser's Back button to go back and enter a new search criteria.

Electronic Orange Book Query

Search by Proprietary Name:
Sephadex (Type in part or all of name)

Select the list you would like to search:

- (•) Rx (Prescription Drug Products)
- ( ) OTC (Over-the-Counter Drug Products)
- ( ) Disc (Discontinued Drug Products)

Submit Clear

Return to the Electronic Orange Book Home Page!

No matching records found. Use your browser's Back button to go back and enter a new search criteria.

Electronic Orange Book Query

Search by Active Ingredient:
acrylate (Type in part or all of name)

Select the list you would like to search:

- (•) Rx (Prescription Drug Products)
- ( ) OTC (Over-the-Counter Drug Products)
- ( ) Disc (Discontinued Drug Products)

Submit Clear

Return to the Electronic Orange Book Home Page

No matching records found. Use your browser's Back button to go back and enter a new search criteria.

Electronic Orange Book Query

Search by Active Ingredient:

acrylate (Type in part or all of name)

Select the list you would like to search:

- ○ Rx (Prescription Drug Products)
- ◉ OTC (Over-the-Counter Drug Products)
- ○ Disc (Discontinued Drug Products)

Submit Clear

Return to the Electronic Orange Book Home Page

No matching records found. Use your browser's Back button to go back and enter a new search criteria.

No matching records found. Use your browser's Back button to go back and enter a new search criteria.

Electronic Orange Book Query

Search by Active Ingredient:
polyacrylate (Type in part or all of name)

Select the list you would like to search:

- (•) Rx (Prescription Drug Products)
- ( ) OTC (Over-the-Counter Drug Products)
- ( ) Disc (Discontinued Drug Products)

Submit Clear

Return to the Electronic Orange Book Home Page

No matching records found. Use your browser's Back button to go back and enter a new search criteria.

Electronic Orange Book Query

Search by Active Ingredient:
polyacrylate (Type in part or all of name)

Select the list you would like to search:

- ○ Rx (Prescription Drug Products)
- ◉ OTC (Over-the-Counter Drug Products)
- ○ Disc (Discontinued Drug Products)

Submit | Clear

Return to the Electronic Orange Book Home Page

No matching records found. Use your browser's Back button to go back and enter a new search criteria.

Electronic Orange Book Query

Search by Active Ingredient:
polyacrylate (Type in part or all of name)

Select the list you would like to search:

- ○ Rx (Prescription Drug Products)
- ○ OTC (Over-the-Counter Drug Products)
- ◉ Disc (Discontinued Drug Products)

Submit Clear

Return to the Electronic Orange Book Home Page

No matching records found. Use your browser's Back button to go back and enter a new search criteria.

ATTACHMENT B